

MODEL STANDING ORDERS

**Immune Globulin (Human) USP
For Hepatitis A Postexposure Prophylaxis**

These model standing orders are current as of February 2004. All standing orders should be reviewed carefully against the most current recommendations and may be revised by the clinician signing them.

Intramuscular (IM) Immune Globulin (IG) is indicated for passive immunization to protect against hepatitis A.

IG is recommended for previously **unvaccinated** persons¹ in the following situations, if it is ≤ 14 days after exposure:

- 1) Household and sexual contacts of persons who have serologically confirmed HAV.
- 2) All staff and attendees of day care centers or homes, including unimmunized new employees and children during the 6 weeks after the last case is identified, if:
 - ≥ 1 case of HAV are recognized in children or staff; or
 - cases are recognized in ≥ 2 households of center attendees.

(In centers that do not provide care for children in diapers, IG need only be given to classroom contacts of the index case. When an outbreak occurs [i.e., HAV in ≥ 3 families], IG should be considered for members of households that have children [center attendees] in diapers.)
- 3) All foodhandlers at a location where a foodhandler has been diagnosed with HAV.
- 4) IG administration to patrons is usually not recommended, but may be **considered** if:
 - During the time when the foodhandler was infectious, the foodhandler both directly handled uncooked foods or foods after cooking and had diarrhea or poor hygienic practices; and
 - Patrons can be identified and treated ≤ 14 days after exposure.
- 5) IG should be **considered** for close contacts of cases in schools, hospitals or other work settings.

However, IG will be **recommended** for close contacts of an index patient if an epidemiological investigation indicates HAV transmission among students in a school or among patients or between patients and staff in a hospital.

¹IG is **not** needed for people who have received at least 1 dose of hepatitis A vaccine at least 4 weeks prior to exposure.

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ORDER:

1. Provide patient, parent or legal representative with a copy of an IG information sheet (an MDPH version is available) or the Hepatitis A Vaccine Information Sheet (VIS), which contains information about IG on the reverse side.
2. Screen for contraindications according to Table 2. The Massachusetts Department of Public Health (MDPH) *Screening Tool for Administration of Immune Globulin (IG) for Postexposure Prophylaxis for Hepatitis A* (Attachment 1) may be used.
3. Give IG 0.02 mL/kg intramuscularly (IM) with a 22-25-gauge needle. **Always check the package insert prior to administration.**
 - a. For children and adults, administer IG in the upper outer quadrant of the gluteal muscle with a 1- to 2-inch needle, depending on the recipient's weight. Direct the needle anteriorly to avoid injury to the sciatic nerve. The deltoid muscle may be used for adults when the dose of IG is not too large and there is sufficient muscle mass.
 - b. For infants, administer IG at a 90° angle in the anterolateral thigh with a 7/8- to 1-inch needle.

IG doses can be calculated based on an individual's weight (1kg = 2.2 lbs) or, in large clinic situations, aggregate weight groups may receive pre-determined IG doses. The following table may be used as a guide.

Table 1. Suggested IG dose per Aggregate Weight Group

Weight	IG Dose
< 55 lbs (< 25 kg)	0.5 ml (or weigh each individual and calculate dose)
55 lbs – 110 lbs (25 kg – 50 kg)	1.0 ml
> 110 lbs to 220 lbs (> 50 kg – 100 kg)	2.0 ml
> 220 lbs (> 100 kg)	3.0 ml

Please note:

- IG should be administered at room temperature.
- No more than 5 mL should be administered in one site in an adult or large child; 1 – 3 mL should be given in one site to small children and infants.

4. Administration of IG and other vaccines:

a. Inactivated Vaccines

IG can be administered simultaneously with, or at any interval before or after, any inactivated vaccine, including hepatitis A vaccine.

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b. Live Vaccines

- **If MMR and/or varicella vaccine has been given within the previous 2 weeks:** The person should receive IG, but should be revaccinated or tested for seroconversion ≥ 3 months later.
- **If IG for hepatitis A postexposure prophylaxis is given first:** The person should be told to wait 3 months before receiving MMR and/or varicella vaccine.

Note: IG can be administered at any interval with, before or after oral typhoid or yellow fever vaccines.

5. If possible, observe patient for an allergic reaction for 15 – 20 minutes after administering IG.
6. Facilities and personnel should be available for treating immediate hypersensitivity reactions.
7. Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or www.vaers.org.
8. Please see the MIP document, *General Protocols for Standing Orders*, for further recommendations and requirements regarding vaccine administration, documentation, and consent.

Table 2. Contraindications to IG

Valid Contraindications for Immune Globulin	Invalid Contraindications (IG should be given)
Anaphylactic reaction to a previous dose of IG	Any illness
History of reactions related to anti-IgA antibodies, or history of IgA deficiency. (In such cases, use of IgA-depleted IGIV may reduce likelihood of further reaction).	Recent exposure to infectious disease
	Current microbial therapy
Persons with severe thrombocytopenia or any coagulation disorder that would preclude IM injection . In such cases, IGIV is preferred.	Pregnancy ¹
	Breast feeding
	Contact allergy to latex
Precautions	
Previous anaphylactic reaction to latex ²	
Receipt of measles, mumps, rubella or varicella vaccine within the previous 2 weeks ³	
Mild to moderate bleeding disorder or taking anticoagulation medication ⁴	

Footnotes on next page.

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- ¹ There is no known risk to the fetus from passive immunization of pregnant women with IG. IG should be given to pregnant women if it is indicated.
- ² A person with a history of an **anaphylactic** reaction to latex should be referred to a health care provider for evaluation and safe administration of IG. For latex allergies other than anaphylactic allergies (e.g., history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex can be administered.
- ³ IG now may interfere with the development of immunity to measles, mumps, rubella and varicella if given within 2 weeks after the vaccines. This person should still receive IG, but should be referred to their health care provider to be revaccinated with MMR or varicella vaccine or be tested for immunity at least 3 months after receipt of IG.
- ⁴ People with a mild to moderate bleeding disorder or taking anticoagulation medication should check with their health care provider before receiving IG in the clinic setting.

<p>Note: A person who received at least 1 dose of hepatitis A vaccine at least 4 weeks prior to exposure does not need to receive IG for post exposure prophylaxis.</p>
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References:

CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices and the American Academy of Family Physicians. MMWR 2002;51(No. RR-2):1-35.

American Academy of Pediatrics. Active and Passive Immunization.. Hepatitis A. In Pickering, LK ed. *Red Book. 2003 Report of the Committee on Infectious Diseases*. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics: 18, 54-56, 311-318.

CDC. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(No. RR-112):26-30.

CDC. Use of vaccines and immune globulins in persons with altered immunocompetence: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1993;42(No. RR-4):1-18.

Chin J, ed. Control of communicable diseases manual. 17th ed. Washington, DC: APHA, 2000:238-43.

Immune Globulin (Human) USP package insert, Massachusetts Public Health Biologic Laboratories, Department of Public Health, The Commonwealth of Massachusetts.

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**MODEL STANDING ORDERS - Immune Globulin (Human) USP
For Hepatitis A Postexposure Prophylaxis – Attachment 1**

Screening Tool for Administration of Immune Globulin (IG)
For Post Exposure Prophylaxis for Hepatitis A

[If IG is being administered as part of a hepatitis A outbreak, a question pertinent to exposure history should be inserted here. If the person was exposed to hepatitis A within the last 2 weeks, they should receive IG to prevent hepatitis A, unless they received at least 1 dose of hepatitis A vaccine at least one month before their exposure to hepatitis A virus.]

Screening Questions	Response	Advice
1. Have you ever received hepatitis A vaccine.	No <input type="checkbox"/> Yes <input type="checkbox"/>	If you received at least 1 dose of hepatitis A vaccine at least one month before your exposure, you are considered protected against hepatitis A and you do not need to receive IG.
2. Have you ever had an <u>anaphylactic</u> reaction to a previous dose of IG?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should speak with your health care provider before getting IG.
3. Have you ever had an <u>anaphylactic</u> reaction to latex?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should talk to your health care provider before getting IG. If you have only a <u>contact</u> or other non-serious allergy to latex, you can receive IG.
4. Have you ever had a reaction related to anti-IgA antibodies, or history of IgA deficiency?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should talk to your health care provider before receiving IG. They may choose to use IgA-depleted IG intravenously (IV) instead of IG given in your arm to reduce the likelihood of further reaction.
5. Do you have a bleeding disorder or take anticoagulant medication?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, you should talk to your health care provider before getting IG. They may decide it is ok for you to receive IG given in your arm, or they may decide you should receive it IV.
6. Have you received measles, mumps, rubella vaccine (MMR) and/or varicella (chicken pox) vaccine in the last 2 weeks?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, receiving IG now may interfere with immunity to measles, mumps, rubella and varicella. You should still receive IG today, but 3 months from now you should be revaccinated with MMR or varicella vaccine or be tested for immunity.
7. Do you plan to receive MMR and/or varicella vaccine in the next 3 months?	No <input type="checkbox"/> Yes <input type="checkbox"/>	You should wait 3 months after receiving IG before getting MMR or varicella vaccine.
8. Do you handle food that is served to people as part of your job or other activity?	No <input type="checkbox"/> Yes <input type="checkbox"/>	If yes, health department staff would like to speak with you. You may need documentation that you received IG in order to return to work.

(See reverse side for definitions.)

Definitions:

Anaphylactic reaction: A potentially life-threatening allergic reaction manifested by generalized urticaria (hives), wheezing, swelling of the mouth and throat, difficulty breathing, hypotension (low blood pressure) and shock.

Anticoagulant medication: Drug used to delay clotting of the blood. Sometimes called a “blood thinner”.

Food handler: A food handler is any person directly preparing or handling food. This could include the owner; individual having supervisory or management duties; other person on the payroll; family member; volunteer; person performing work under a contract; or any other person working in the food handling facility. In health care facilities, this includes those who set up trays for patients to eat; those who feed or assist patients in eating; those who give oral medications; and those who give mouth care. In day care facilities, schools, and community residential programs, this includes those who prepare food for clients to eat; feed or assist clients in eating; or give oral medications. (*105 CMR 300: Isolation and Quarantine Regulations*)

Latex: Latex is a liquid sap from the commercial rubber tree and contains naturally-occurring impurities such as plant proteins, which are believed to be responsible for allergic reactions. Natural rubber latex and dry natural rubber may contain the same plant impurities as latex. Dry natural rubber is used in some syringe plungers, vial stoppers and IV tubing.